

REMARKS/ARGUMENTS

Upon entry of this amendment, claims 30-41 are pending in this application and are presented for examination. Claims 1-29 have been canceled without prejudice. Claims 30-41 are newly added. No new matter has been introduced with the foregoing amendments. Reconsideration is respectfully requested.

I. FORMALITIES

Applicant thanks the Examiner for the telephone interview of January 13, 2005, in which proposed amendments to claim 5 were discussed.

Support for new claims 30-41 is found throughout the specification as filed. In particular, support for new claims 30-37 is found, for example, on page 2, lines 15-28, on page 3, lines 19-37, and on page 42, lines 25-34. Support for new claim 38 is found, for example, on page 6, lines 25-28. Support for new claim 39 is found, for example, on page 42, lines 17-24. Support for new claims 40-41 is found, for example, on page 45, lines 11-19 and 24-28. Thus, no new matter has been introduced. As such, Applicant respectfully requests that the new claims be entered.

II. THE INVENTION

The present invention is drawn to a method for determining an IBD or pre-IBD phenotype of a test cell from a given tissue comprising contacting the mRNA of the test cell with at least 5 different nucleic acid probes, wherein each probe is at least 12 nucleotides in length and is complementary to the mRNA of a gene shown in Table 1; and determining an approximate amount of hybridization between each probe and the mRNA of the gene shown in Table 1, wherein the amount of hybridization either more or less relative to a control cell of the given tissue type indicates that the test cell has an IBD or pre-IBD phenotype.

III. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 5-7 and 19-29 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled the art that Applicant, at the time the application was filed, had possession of the claimed invention. In response, Applicant has canceled claims 5-7 and 19-29 without prejudice, thereby rendering this rejection moot. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Newly added claims 30-41 recite contacting the mRNA of a test cell with at least 5 different nucleic acid probes, wherein each probe is at least 12 nucleotides in length and is complementary to the mRNA of a gene shown in Table 1. Applicant submits that the specification as filed contains adequate written description of the nucleic acid probes used in the claimed invention. In particular, the specification describes nucleic acid probes of at least 12 nucleotides in length having a sequence complementary to a nucleic acid sequence set forth in Table 1, in which the nucleic acid sequence is provided by a GenBank accession number (*see*, page 42, lines 10-16; Table 1, under "Accession No."). The specification also discloses that these nucleic acid probes generally hybridize under stringent conditions to the nucleic acid sequence and are at least about 80% identical to the nucleic acid sequence (*see*, page 3, lines 26-37). Further, the specification describes that these nucleic acid probes are useful for determining an IBD or pre-IBD phenotype of a test cell from a given tissue (*see*, page 42, lines 25-34). In view of the foregoing, Applicant asserts that the nucleic acid probes used in the claimed invention are adequately disclosed in the specification as filed.

IV. REJECTION UNDER 35 U.S.C. § 103(a)

Claims 5-7 and 19-29 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Alexander *et al.* (*Digestive Diseases and Sciences*, 41:660-669 (1996)) in view of Puolakkainen *et al.* (*Gastroenterology*, 114:A1064 (1998)) and Prehn *et al.* (*Gastroenterology*, 114:A1064 (1998)). Applicant has canceled claims 5-7 and 19-29 without prejudice, thereby rendering this rejection moot. Thus, Applicant respectfully requests that this rejection be withdrawn.

Newly added claims 30-41 recite contacting the mRNA of a test cell with at least 5 different nucleic acid probes, wherein each probe is at least 12 nucleotides in length and is

complementary to the mRNA of a gene shown in Table 1. These claims further recite determining an approximate amount of hybridization between each probe and the mRNA of the gene shown in Table 1, wherein the amount of hybridization either more or less relative to a control cell, *i.e.*, the presence of differential expression of at least 5 different genes shown in Table 1, indicates that the test cell has an IBD or pre-IBD phenotype. Although Alexander *et al.* discloses the differential expression of *H-ras*, *c-myc*, *c-fos*, *c-jun*, *junB*, *N-myc*, *c-abl*, and *c-yes* in colonic epithelial cells of IBD patients, this reference simply fails to teach or suggest determining the presence of differential expression of any of the genes shown in Table 1. Similarly, Prehn *et al.* does not teach or suggest determining the presence of differential expression of any of the genes shown in Table 1. In fact, this reference discloses the absence of differential expression of IL-18, IL-12, IL-10, and IL-4 in cells treated with TNF- α . Further, Puolakkainen *et al.* discloses the differential expression of stromelysin-2 (MMP-10), collagenase-3 (MMP-13), macrophage metalloelastase (MMP-12), and TIMP-3 in intestinal ulcerations, but does not teach or suggest determining the presence of differential expression of at least 5 different genes shown in Table 1. As a result, Applicant asserts that these three references, either alone or in combination, fail to teach or suggest the claimed invention.

Claims 5-7 and 19-29 were also rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Dieckgraefe *et al.* (*Gastroenterology*, 114:A964-965 (1998)). Applicant has canceled claims 5-7 and 19-29 without prejudice, thereby rendering this rejection moot. As such, Applicant respectfully requests that this rejection be withdrawn.

As discussed above, newly added claims 30-41 recite contacting the mRNA of a test cell with at least 5 different nucleic acid probes, wherein each probe is at least 12 nucleotides in length and is complementary to the mRNA of a gene shown in Table 1. These claims further recite determining an approximate amount of hybridization between each probe and the mRNA of the gene shown in Table 1, wherein the amount of hybridization either more or less relative to a control cell, *i.e.*, the presence of differential expression of at least 5 different genes shown in Table 1, indicates that the test cell has an IBD or pre-IBD phenotype. Although Dieckgraefe *et*

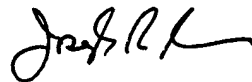
al. discloses the differential expression of different classes of genes including cell adhesion molecules and reparative factors in IBD specimens, this reference simply fails to teach or suggest determining the presence of differential expression of any of the specific genes shown in Table 1. As such, Applicant asserts that this reference does not teach or suggest the claimed invention.

V. CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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